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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/024,066 | 12/18/2001 | Loren J. Field | 7037-450 | 3713 |

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Kenneth A. Gandy
Woodard, Emhardt, Naughton, Moriarty & McNett
Bank One Center/Tower, Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

| EXAMINER | |
|---|---|
| SULLIVAN, DANIEL M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/024,066 | FIELD ET AL. | |
| | Examiner | Art Unit | |
| | Daniel M Sullivan | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19 and 35-42, drawn to a method for increasing the proliferative potential of a cardiomyocyte comprising increasing the level of cyclin D2 activity, classified in class 435, subclass 440.

II. Claims 20-28, drawn to a cardiomyocyte having introduced nucleic acid encoding a cyclin D2 protein, classified in class 435, subclass 325.

III. Claims 29-34, drawn to a nucleic acid construct having a sequence of nucleotides encoding a cyclin D2 protein operably linked to an inducible promoter, classified in class 536, subclass 23.5.

IV. Claims 43-45, drawn to a method for providing proliferative cardiomyocytes in a mammal, classified in class 424, subclass 93.1.

V. Claim 46, drawn to a transgenic non-human mammal having cardiomyocytes expressing introduced DNA encoding a cyclin D2 protein, classified in class 800, subclass 14.

VI. Claim 47, drawn to a modified D-type cyclin protein, classified in class 530, subclass 352.

VII. Claim 48, drawn to a nucleic acid molecule encoding a modified D-type cyclin of Group VI, classified in class 536, subclass 23.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make a materially different product because the process encompasses increasing the level of cyclin D2 activity by means other than introducing a nucleic acid encoding a cyclin D2 protein (see, e.g., the paragraph bridging pages 21-22 of the specification).

Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, as above, the process does not require administering the nucleic acid of Group III because the specification teaches that it can also be practiced using pharmacological agents.

Inventions IV and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of Group IV is not limited to increasing the level of cyclin D2

activity in the cardiomyocytes according to Group I. The subcombination has separate utility such as in the production of proliferating cardiomyocytes for *in vitro* analyses.

Inventions I and V are related as process of making and product made. As above, the process as claimed can be used to make a materially different product because the process encompasses increasing the level of cyclin D2 activity by means other than introducing a nucleic acid encoding a cyclin D2 protein .

Inventions VI and VII are related to Invention I as product and process of using. As above, the process does not require expression of the protein of Group VI or administering the nucleic acid of Group VII because the specification teaches that it can also be practiced using pharmacological agents.

The nucleic acid of Invention III, the protein of Invention VI and the nucleic acid of Invention VII are related to Invention II as combination and subcombination. The combination as claimed does not require the particulars of the subcombinations because the nucleic acid comprised within the cardiomyocyte of Group II need not comprise the inducible promoter to which the nucleic acid of Group III is limited and need not comprise a modified D-type cyclin protein according to the limitations of Groups VI and VII. The subcombinations have separate utility such as the expression of cyclin D2 or a modified D-type cyclin in non-cardiomyocytes or *in vitro*.

The cell of Invention II, nucleic acid of Inventions III and VII and protein of Invention VI are related to the method of Invention IV as product and process of use. However, the products of can be used in a materially different process such as to provide proliferating

cardiomyocytes *in vitro* and the process can be practiced using materially different products such as pharmacological agents (*Id.*).

The cell of Invention II is related to the transgenic animal of Invention V in that the animal comprises the cell of Invention II. However, the cell has separate utility such as for use in *in vitro* assays. Furthermore, patentability of the transgenic animal arises from the overall phenotypic characteristics of the animal; thus, patentability of the transgenic animal is not solely dependent upon the particulars of the cardiomyocytes comprised within the animal.

Likewise, the transgenic animal of Invention V is related to the nucleic acids of Inventions III and VII and the protein of Invention VI in that the animal can be produced using the nucleic acid of Invention I and comprises the protein of Invention III. The animal is distinct from the protein and nucleic acid, however, because they are physically and functionally distinct and the peptide and nucleic acid can be used for processes other than production of the transgenic animal, such as to raise antibodies, or screen for agents that bind to the protein or nucleic acid. Furthermore, patentability of the transgenic animal arises from the phenotypic characteristics of the animal; thus, patentability of the transgenic animal is not solely dependent upon the particulars of the nucleic acid or polypeptide comprised within the animal.

The nucleic acid of Invention III is distinct from the polypeptide of Invention VI and the nucleic acid of Invention VII. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and the Groups are directed to genera having mutually exclusive properties. The protein of Group VI and nucleic acid of Group VII are

explicitly limited to encoding a modified D-type cyclin, while the nucleic acid of Group III is not, and the nucleic acid of Group III is explicitly limited to encoding a cyclin D2 protein, while the protein and nucleic acid of Groups VI and VII are not. Furthermore, the nucleic acid of Group III is limited to being operably linked to an inducible promoter, while the nucleic acid of Group VII is not.

Invention V is related to Invention IV as product and process of making. However, the process as claimed can be used to make a materially different product because the product of Invention IV need not have cardiomyocytes expressing an introduced DNA encoding cyclin D2 and, in fact, need not express cyclin D2 at all.

Finally, the nucleic acid of Invention VII is related to the protein of Invention VI by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER